IN THE UNITED STATES	DISTRICT COURT
FOR THE DISTRICT OF M	MASSACHUSETTS

KATHLEEN A. MARTIN,

Plaintiff,

CIVIL ACTION No. 05-11716-MLW

v.

MERCK & CO., INC., et. als.

Defendants.

MOTION OF THE DEFENDANTS, DARTMOUTH HITCHCOCK MEDICAL CENTER,
ROSHINI PINTO POWELL, M.D. AND CHARLES CARR, M.D. TO DISMISS
PURSUANT TO F.R. CIV. P. RULE 12(b)(2) OR, IN THE ALTERNATIVE, FOR
REMAND OF THE CLAIMS AGAINST THEM TO THE MASSACHUSETTS
SUPERIOR COURT

Defendants, Dartmouth Hitchcock Medical Center, Roshini Pinto Powell, M.D., and Charles Carr, M.D. (hereinafter, "the New Hampshire defendants"), through undersigned counsel hereby move this Court pursuant to F.R. Civ. P. Rule 12(b)(2) to dismiss this action against them for lack of personal jurisdiction. These defendants submit that diversity of citizenship between the plaintiff and defendants, while necessary to confer **subject matter** jurisdiction on this Court pursuant to 28 U.S.C., S.1332, is not sufficient to vest this Court with **personal jurisdiction** over these defendants. The New Hampshire defendants are citizens of a foreign state and their only alleged contacts with plaintiff took place in that foreign State; there is no basis consistent with the Massachusetts long-arm statute or due process which would permit the exercise of jurisdiction over the person of these three defendants by a Massachusetts court, whether State or Federal.

In addition, and/or in the alternative, the New Hampshire defendants move that this Court

sever the claims against them and remand those claims to the Massachusetts Superior Court, or remand the entire case, on the grounds that:

- Removal to this Court was improperly accomplished by co-defendant Merck with-1. out the consent of the New Hampshire defendants, and indeed with full knowledge of the express objection of these defendants to removal, and despite the pendency in the state court of these defendants' Mass. R. Civ. P. Rule 12(b)(2) motion to dismiss for lack of personal jurisdiction;
- 2. If this Court or the Massachusetts Superior Court were to determine that personal jurisdiction does exist over these defendants, the substantive law of Massachusetts entitles these defendant to the convening of a medical malpractice tribunal pursuant to M.G.L. Chapter 231, Section 60B, a proceeding which must be held in the Massachusetts Superior Court. If this matter is not remanded and ends up transferred to the Vioxx® Multi-District Litigation in New Orleans, the medical defendants will be unjustly denied their statutory right to a preliminary tribunal determination as to the alleged merits of the claims against them;
- 3. From the face of the complaint, it appears that the allegations against Merck are of a failure to disclose certain alleged cardiovascular risks of Vioxx® to the general public and to prescribing physicians, whereas the vaguely asserted claims against the New Hampshire defendants appear to be of failure to disclose those unspecified Vioxx® risks as to which they were in fact already aware. As such, the claims against the New Hampshire defendants are separate and distinct from the claims against Merck, and thus do not involve common questions of law or fact arising from the same transaction, occurrence of series of transactions or occurrences, necessary for proper joinder under F.R. Civ. P. Rule 20. Conversely, the prejudicial effect and undue additional burden, inconvenience and expense which would be incurred by the New Hampshire defendants from being obliged to defend themselves through unfamiliar national liaison coordinating counsel in a monstrously complex MDL in Louisiana which involves thousands of cases not even remotely related to the claims apparently asserted against the New Hampshire defendants in the present case would be unjust to the extreme.

As further grounds for the within motion, defendants herein submit the accompanying Memorandum of Law.

STATEMENT PURSUANT TO LOCAL RULE 7.1(A)(2)

Undersigned counsel for the New Hampshire defendants has conferred with counsel for the plaintiff with respect to the within Motion to Dismiss and with counsel for Merck with respect to the request for remand and/or severance and remand, and has been unable to reach agreement with either counsel with respect to either aspect of this motion.

REQUEST FOR ORAL ARGUMENT

The New Hampshire defendants respectfully requests the opportunity to be heard at oral argument with respect to the within motion, unless this Court sees fit to grant said motion on the papers alone.

> Respectfully submitted By their attorneys

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CERTIFICATE OF SERVICE

I hereby certify that on this 16th day of 9eth, 2005, I caused the within Motion to be mailed first-class United States mail, postage prepaid, to Andrew J. Tine, Esquire, Haese, LLC, 30 Federal Street, Third Floor, Boston, MA 02110; Lucy Fowler, Esquire, Foley Hoag, LLP, Seaport World Trade Center West, 155 Seaport Boulevard, Boston, MA 02210-2600; and Maria Mazur, Esquire, Martin, Magnuson, McCarthy & Kenney, 101 Merrimack Street, Boston, MA 02114-4716

John M. Dellea, Esquire

COMMONWEALTH OF MASSACHUSETTS

ESSEX, SS.		SUPERIOR COURT
		C. A. NO. ESCV 2005-00641-D
KATHLEEN A. MARTIN)	
Plaintiff)	
)	
v.)	MEMORANDUM OF LAW IN SUPPORT
)	OF MOTION OF DEFENDANT, BRIGHAM
MERCK & CO., INC., DARTMOUTH-)	AND WOMEN'S HOSPITAL, TO DISMISS
HITCHCOCK MEDICAL CENTER,)	PLAINTIFF'S CLAIMS PURSUANT TO
DR. ROSHINI PINTO POWELL,)	FED. R. CIV. P. 8(a)(2) and (e)(1) and
DR. CHARLES CARR, BRIGHAM)	12(b)(6)
AND WOMEN'S HOSPITAL AND)	
DR. PETER J. MILLETT,)	
Defendants)	

I. INTRODUCTION

On April 21, 2005, the plaintiff, Kathleen A. Martin, filed a Complaint naming Brigham and Women's Hospital as a party defendant in the above-captioned case. (Complaint attached hereto as Exhibit "1"). The trial court docket indicates that on July 25, 2005, service was effected on the defendant, Brigham and Women's Hospital. By this Motion, counsel for the defendant, Brigham and Women's Hospital, submits that the Complaint fails to give notice of the plaintiff's claims and the grounds upon which they rest as to the defendant, Brigham and Women's Hospital.

II. ARGUMENT

The Federal Rules of Civil Procedure state that claims for relief shall contain a "short and plain statement of the claim showing that the pleader is entitled to relief" and each averment "shall be simple, concise, and direct." Fed. R. Civ. P. 8(a)(2) and 8(e)(1). Pursuant to Fed. R. Civ. P. 41(b), the Court has discretion to dismiss any action for failure of the plaintiff to comply

with these rules. Defendants are entitled to this discretion when the Complaint fails to give the defendants fair notice of plaintiff's claims and the grounds upon which they rest. Mmoe v. Commonwealth, 393 Mass. 617, 621 (1985), citing, Conley v. Gibson, 355 U.S. 41, 47 (1995). It is within the discretion of the Court to dismiss a complaint with prejudice for failure to comply with the rules of civil procedure. <u>Id.</u>

In her Complaint, Ms. Martin has failed to state any claim against the defendant, Brigham and Women's hospital. On the first page of the Complaint, the plaintiff provides a three sentence opening summary. The last sentence of the opening summary states: "This action is also brought based on the actions or inactions of the Dartmouth-Hitchcock Medical Center and Brigham and Women's Hospital in allowing the drug to be prescribed to Plaintiff . . ." (emphasis added). This is the only specific reference in the entire 91 Paragraph Complaint that identifies the defendant, Brigham and Women's Hospital. However, that sentence alone clearly fails to give fair notice of what the plaintiff's claims are and the grounds upon which they rest. Moreover, Counts I, III, IV, V and VI of the Complaint are specifically directed to other party defendants. It is speculative at best as to whom the plaintiff refers in Paragraph 67 of Count II (Medical Monitoring) which states in pertinent part:

"As a direct and proximate result of *Defendants*' acts and omissions as set forth herein, Plaintiff was exposed to hazardous substance, and, as a result, now suffers a significantly increased risk of contracting further serious injury or latent disease, including heart attack and stroke." (emphasis added)

Counsel for defendant, Brigham and Women's Hospital, submits that these non-specific references fail to provide fair notice of the claims against Brigham and Women's Hospital and that the plaintiff has clearly failed to state a claim upon which relief may be granted.

Dismissal of the Complaint in this case is appropriate as it appears beyond doubt that Ms. Martin "can prove no set of facts in support of h[er] claim which would entitle h[er] to relief." Nader v. Citron, 372 Mass. 96, 98 (1977) (citations omitted). The plaintiff's claim must be set forth in the complaint; all material outside the pleadings are excluded. Mass. R. Civ. P. 12(b). The factual allegations in the complaint will be treated as true, and the plaintiff is entitled to all favorable inferences. General Motors Acceptance Corp. v. Abington Cas. Ins. Co., 413 Mass. 583, 584 (1992) (citations omitted). The general statement made as to the Brigham and Women's Hospital "in allowing the drug to be prescribed" is so non-specific and clearly fails to give fair notice of the claims and grounds upon which they rest.

Ш. CONCLUSION

For the reasons stated above, the defendant, Brigham and Women's Hospital, respectfully requests this Court to grand this Motion and dismiss plaintiff's Complaint against it with prejudice.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I, Maria L. Mazur, counsel for defendant, Peter J. Millett, M.D, hereby certify that on the 13th day of September, 2005, I served the foregoing by mailing a copy thereof, postage prepaid to:

Andrew Tine, Esq. Haese, LLC 30 Federal Street, 3rd Floor Boston, MA 02110

John Dellea, Esq. Ficksman & Conley 98 N. Washington Street Boston, MA 02114 James Dillon, Esq. Foley Hoag, LLP 155 Seaport Boulevard Boston, MA 02210

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COMMONWEALTH OF MASSACHUSETTS

ESSEX, ss	SUPERIOR COURT CIVIL ACTION NO.:
KATHLEEN A. MARTIN,) Plaintiff,)	
v.)	
MERCK & CO., INC., DARTMOUTH) -HITCHCOCK MEDICAL CENTER,)	
DR. ROSHINI PINTO POWELL,) DR. CHARLES CARR, BRIGHAM AND)	
WOMEN'S HOSPITAL and DR. PETER J.) MILLETT,	
Defendants.)	

COMPLAINT AND JURY DEMAND

This is an action brought by Plaintiff for damages resulting from the ingestion of the non-steroidal, anti-inflammatory pain medication called Vioxx (chemical name "rofecoxib"). This action seeks damages and the establishment of a medical monitoring program on behalf of the Plaintiff for the diagnosis and treatment of Vioxx-related adverse health effects from which Plaintiff presently suffers. This action is also brought based on the actions or inactions of the Dartmouth-Hitchcock Medical Center and Brigham and Women's Hospital in allowing the drug to be prescribed to Plaintiff as well as the specific actions of Dr. Roshini-Pinto Powell and Dr. Peter J. Millet in prescribing the medication and/or failing to provide the proper treatment to Plaintiff.

I. INTRODUCTION

1. Plaintiff Kathleen A. Martin ("Martin") brings this civil action for damages and medical monitoring as a result of harm suffered from (a) the purchase and use of Vioxx;

(b) the increased risk of health problems causally connected to the consumption of

Vioxx; and (c) the actual health problems already experienced by Plaintiff as a result of the consumption of Vioxx.

- 2. Plaintiff purchased Vioxx and ingested the drug on a regular basis, as prescribed by her physicians, Dr. Roshini Pinto-Powell, Dr. Charles Carr, and Dr. Peter Millet. At all times relevant hereto, Defendants Dr. Roshini Pinto-Powell and Defendant Dr. Charles Carr were employed and/or otherwise affiliated with the Defendant Dartmouth-Hitchcock Medical Center. At all relevant times hereto, Defendant Dr. Peter Millet was employed and/or otherwise affiliated with the Defendant Brigham and Women's Hopsital.
- 3. Ingestion of Vioxx has been linked to an increased risk of adverse health effects for users, including the increased risk of cardiovascular events such as heart attack, stroke, and risk of GI bleeding.
- 4. The Food and Drug Administration ("FDA") approved Vioxx in 1999 for the reduction of pain and inflammation caused by osteoarthritis, as well as for acute pain in adults and for the treatment of menstrual pain. The FDA accelerated the approval process of Vioxx because of a perceived benefit to consumers over the available alternatives at the time, including ibuprofen and naproxen. Subsequently, the FDA approved Vioxx to treat the signs and symptoms of rheumatoid arthritis in adults and children.
- 5. In June 2000, Merck & Co. Inc. ("Merck") submitted to the FDA a safety study called VIGOR (Vioxx Gastrointestinal Outcomes Research) that found an increased risk of serious cardiovascular events including heart attacks and strokes, in patients taking Vioxx compared to patients taking naproxen. Defendant Merck attributed these results to a purported "cardio-protective effect" of naproxen.

- 6. Despite reports over the next few years to the contrary, Defendant Merck continued to maintain that Vioxx did not increase a user's risk of cardiovascular events such as heart attack and stroke.
- 7. On September 30, 2004, Defendant Merck revealed that Vioxx doubled the risk of heart attack and stroke to consumers who took the drug for longer than 18 months, as compared to subjects taking a placebo. As a result of this revelation, Vioxx was withdrawn from the market worldwide.
- 8. However, the withdrawal from the market came after Plaintiff Kathleen A. Martin ingested the drug without notice of the inherent risks to her health. As such, Plaintiff suffered harm in that her consumer choice was distorted by misleading representations by Defendant Merck, and now Plaintiff is at increased risk of cardiovascular events, such as heart attack and stroke, and thrombosis, hemorrhage, and drainage to GI track, and thus requires medical monitoring.

II. PARTIES

- 9. Plaintiff Kathleen A. Martin is currently a resident of the Commonwealth of Massachusetts and acquired and ingested Vioxx while first a resident of Vermont and later of Rockport, Massachusetts.
- 10. Defendant Merck & Co., Inc. describes itself as a global research-driven pharmaceutical company which discovers, develops, manufactures and markets a broad range of products to improve human and animal health, directly and through joint ventures. Merck is incorporated under the laws of the State of New Jersey with its principal place of business at One Merck Drive, Whitehouse Station, New Jersey.

Defendant was in the business of profiting from the design, manufacture, marketing, distribution and/or sales of the brand-name prescription drug Vioxx.

- 11. Defendant Dartmouth Hitchcok Medical Center is a patient treatment medical facility organized under the law of the State of New Hampshire with its principal place of business located at One Medical Center Drive, Lebanon, New Hampshire.
- 12. Defendant Brigham and Women's Hospital is a medical facility organized under the laws of the Commonwealth of Massachusetts with its principal place of business located at 75 Francis Street, Boston, Massachusetts.
- 13. Defendants Dr. Roshini-Pinto Powell and Dr. Charles Carr are medical doctors affiliated with and practicing under the auspices of the Defendant Dartmouth-Hitchcock Medical Center, both with business addresses of One Medical Drive, Lebanon, New Hampshire.
- 14. Defendant Dr. Peter Millet is a medical doctor affiliated with and practicing under the auspices of the Defendant Brigham and Women's Hospital, with a business address of 75 Francis Street, Boston, Massachusetts.

III. FACTUAL BACKGROUND

- 15. At all times relevant, Defendant Merck, itself or by use of others, did distribute, market, sell, promote, advertise, and otherwise distribute in the Commonwealth of Massachusetts, the pharmaceutical product Vioxx.
- 16. Vioxx belongs to a class of drugs called "non-steroidal anti-inflammatory drugs," or "NSAIDs." NSAIDs reduce pain by blocking the body's production of enzymes called cyclooxygenase, or "COX." of which there are two forms: COX-1 and COX-2. Most traditional NSAIDs (such as ibuprofen and naproxen) work by blocking the

COX-1 enzyme, which reduces pain but may lead to gastroinstestinal perforations and bleeds.

- 17. Vioxx, it is believed, blocks the COX-2 enzyme that triggers pain and inflammation while sparing the COX-1 enzyme that helps maintain normal stomach lining. It is indicated for treating the signs and symptoms of osteoarthirtis and rheumatoid arthritis, management of acute pain in adults, and treatment of primary dysmenorrhea.
- 18. Vioxx did not promise to be any more effective than traditional NSAIDs, like ibuprofen and naproxen, at treating inflammation and pain. The sole advantage of Vioxx over other NSAIDs was its purported improved safety profile.
- 19. Vioxx is a brand name used by Merck to market and distribute rofecoxib.

 Vioxx was approved for marketing based on information in the New Drug Application submitted by Merck to the FDA. The FDA put Vioxx on a fast-track approval process that lasted approximately 6 months. Merck obtained FDA approval on Vioxx in or around May of 1999 and began its distribution and sale throughout the United States, including Massachusetts, in or about May of 1999.
- 20. Merck concealed the serious cardiovascular risks associated with Vioxx because a successful launch of Vioxx was viewed as critical for Merck and safety concerns over hypertension, edema and/or cardiovascular events would have drastically impacted positioning in the market as compared to the competing drug, Celebrex (clecoxib), which was placed into the market by Merck competitors Pharmacia and Pfizer some three months prior to the launch of Vioxx.

- 21. Merck knowingly chose to place these adverse health risks on its consumers despite its knowledge at product launch and in post-marketing data thereafter that use of Vioxx carried significant risk factors. These adverse effects were realized in adverse event reports, in clinical trials adjudicated by primary investigators with Merck's assistance, and in one or more studies shortly after market launch, which showed statistically significant increases in adverse cardiovascular events among Vioxx users.
- On or about December 16, 1999, the FDA called Merck to task for its materially false and misleading marketing and promotional materials. The FDA sent Merck an official letter (the "First FDA Warning Letter") admonishing it that the "promotion pieces... that promoted VIOXX (rofecoxib) ... are false and misleading because they contain misrepresentations of VIOXX's safety profile, unsubstantiated comparative claims, and are lacking in fair balance."
- 23. In March 2000, Merck released the results of a Merck-sponsored VIGOR Study, which had begun in or around January of 1999. The VIGOR Study revealed, among other things, "significantly fewer heart attacks were observed in patients taking Naproxen (0 percent) compared to the group taking VIOXX 50 mg (0.5 percent) in this study. There was no difference in cardiovascular mortality between the group treated with VIOXX or Naproxen."
- 24. Merck attributed the difference in rates of cardiovascular events to the fact that riaproxen has "cardio-protective effects," and not to an increased risk of cardiovascular events attributable to Vioxx.

- 25. In designing the VIGOR Study, Merck took the exceptional step of including an "external Vascular Event Committee (VEC), containing three separate subspecialty committees (cardiac, cerebrovascular, and peripheral), [] for surveillance, monitoring, and adjudication of vascular events occurring in COX-2 inhibitor trials." According to a July 13, 2002 article that appeared in the British medical journal, *The Lancet*, Merck "apparently was aware of possible myocardial toxicity before the [VIGOR] trial, because it set in place a separate adjudication procedure to study the event."
- 26. While VIGOR did demonstrate that Vioxx reduced the incidence of serious gastrointestinal side effects as compared to naproxen, it did not demonstrate an improved safety profile for Vioxx. The VIGOR data revealed that:
- a. Patients on Vioxx were five times more likely to suffer a heart attack as compared to patients on naproxen;
- b. Patients on Vioxx were 2.3 times more likely to suffer serious cardiovascular disease (including heart attacks, ischemic stroke, unstable angina, and sudden unexplained death) as compared to patients on naproxen;
- c. According to the FDA. [e]valuation of safety by routine parameters showed no advantage of [vioxx] rofecoxib over Naproxen; and
- d Patients on Vioxx actually suffered *more* cases of serious disease (either gastrointestinal or cardiovascular) than did naproxen users (61 and 57 cases respectively).
- 27. In industry sponsored studies presented at the European United League Against Rheumatism (EULAR), an organization in which Merck is a member and corporate sponsor, in June of 2000, it was shown that Vioxx use resulted in a statistically significant increase in hypertension and myocardial infarction. Merck denied these

studies as to the hypertension problems in the official publication of the American Pharmaceutical Association, Pharmacy Today. (Spin War Aside, Lessons Emerge From Cox-2 Trials, August 2000, page 3).

- 27. Merck continued to deny the ill health effects associated with Vioxx while at the same time reaping the profits obtained through the non-disclosure. Merck engaged in a massive advertising and sampling program and gained continued increases in market share, which enhanced Merck's financial bottom line. The effect was a more than \$2 billion profit for Merck in 2000 and a 23 percent market share.
- 28. Merck continued to withhold relevant data from the public throughout the Class Period. For example, in November of 2000, Merck caused the publication of a study in the New England Journal of Medicine and knowingly downplayed and/or withheld from this publication the severity of cardiovascular risks associated with Vioxx consumption over Naproxen consumption.
- 29. On February 8, 2001, Merck submitted the results of the VIGOR Study to the FDA Arthritis Advisory Committee as part of Merck's application to modify the prescribing information for Vioxx to reflect the Drug's purported gastrointestinal ("GI") benefits
- 30. In considering the VIGOR Study results, however, the FDA Advisory Committee concluded (in February 2001) Vioxx has no safety advantage over the generic drug naproxen, a drug that sells for a fraction of the cost of Vioxx. According to the FDA Advisory Committee Briefing Document, VIOXX Gastrointestinal Safety, dated February 8, 2001: "[I]n the VIGOR Study the potential advantage of decreasing the risk of

complicated [GI side effects] was paralleled by the increased risk of developing cardiovascular thrombotic events."

- 31. According to a memo prepared by an Advisory Committee member, Lourdes Villalba, M.D., dated February 8, 2001, which discusses the "Overall Safety" of Vioxx, "the VIGOR Study found there were more overall deaths among Study participants taking Vioxx than those taking naproxen (22 and 15, respectively).
- 32. The VIGOR results showed that 50mg doses of Vioxx increased the risk of heart attacks and cardiovascular disease. Faced with this treat to the success of its new blockbuster drug, Defendant Merch offered an unfounded explanation for the negative cardiovascular findings of the VIGOR Study. Defendant Merck asserted that the dramatically increased risk of heart attacks in persons taking Vioxx 50mg was not due to Vioxx; rather, Defendant Merck claimed naproxen was cardio-protective and thus dramatically reduced the risk of heart attacks. Tellingly, the marketers of naproxen have never promoted their drug as being cardio-protective.
- 33. On August 22, 2001, the Journal of the American Medical Association

 ("JAMA") published an article authored by cardiologists Eric J. Topol and Steven E.

 Nessen of the Cleveland Clinic Foundation entitled "Risk of cardiovascular Events

 Associated With Selective Cox-2 Inhibitors," which reported the results of a study of

 Vioxx and Celebrex. The JAMA article reported the findings of the Cleveland Clinic's

 study that "current data would suggest that use of these so-called 'COX-2 inhibitors'

 might lead to increased cardiovascular events."

- 35. In a follow-up study reported in the Journal of the American College of Cardiology on or about February 6, 2002, Dr. Richard J. Bing conducted scientific testing and confirmed that the Cox-2 inhibitor tips the balance of prostacyclinlthromboxane in favor of thromboxane, leading to increased vascular and thrombotic events.
- 36. In September 2001, the FDA sent Defendant another warning letter (the "Second FDA Warning Letter") which again warned Defendant that Merck's marketing of VIOXX was "false, lacking in fair balance, or otherwise misleading..." The Second Warning Letter went on to advise Merck that Merck's marketing "minimize[s] the potential serious cardiovascular findings that were observed in the VIGOR Study. minimize[s] the VIOXX/Coumadin drug interaction, omit[s] crucial risk information associated with VIOXX therapy, contain[s] unsubstantiated comparative claims, and promote[s3 unapproved uses."
 - 37. The Second Warning Letter also reprimanded Merck for:

"assert[ing] that Vioxx does not increase the risk of [heart attacks] and that the VIGOR finding is consistent with naproxen's ability to block platelet aggregation like aspirin. That is a possible explanation, but you fail to disclose that your explanation is hypothetical, has not been demonstrated by substantial evidence, and that there is another reasonable explanation, that Vioxx may have pro-thrombotic properties."

- 38. Merck denied reports concerning the increased risk of cardiovascular problems as inaccurate and inconclusive. For example, on May 22, 2001, Merck issued a press release through the PR Newswire that stated, among other things: "In response to news and analyst reports of data the Company first released a year ago, Merck & Co., Inc. today reconfirmed the favorable cardiovascular safety profile of Vioxx."
- 39. The theory that naproxen had a cardioprotective effect and therefore accounted for the higher cardiovascular risks among Vioxx users was debunked in approximately January of 2002 by a Vanderbilt University School of Medicine human epidemiologic peer-reviewed study. The study was published in The Lancet, and concluded that there is an absence of a protective effect of naproxen or other non-aspirin non-steroidal antiinflammatory drugs on risk of coronary heart disease. Ray, W., et. at., Non-Steroidal Anti-Inflammatory Drugs and Risk of Serious Coronary Heart Disease: An Observational Cohort Study, The Lancet, 359: 118-123, Jan. 12, 2002.
- 40. The FDA's Adverse Reporting System ("AERS") database is a computerized system for collecting and maintaining information about adverse events reported by drug manufacturers, health professionals, and others. The system contains adverse events detected and reported after marketing of the drug.
- 41. According to AERS, through October of 2003, almost 2,000 adverse cardiovascular events were experienced by persons taking Vioxx, including myocardial infarctions, cardiac arrests, and cardiac failures. These cardiac events reported to the FDA, which, according to some measures, represent underreporting of as much as 99%, resulted in such outcomes as hospitalization, life threatening conditions, and even death.

- 42. On October 22, 2003, Reuters published an article that stated "arthritis drug is suffering from clinical trial data suggesting it might slightly raise the risk of heart attacks, and the growing perception that its pain-fighting capabilities are no better than traditional painkillers."
- 43. On October 30, 2003, in an article entitled "Vioxx Study Sees Heart-Attack Risk," *The Wall Street Journal* reported that another study, sponsored by Merck, presented at the annual meeting of the American College of Rheumatology, confirmed an increased "risk of heart attacks in patients taking the pill [Vioxx]." According to *The Wall Street Journal* article, within the first 30 days of taking Vioxx, the risk of a heart attack was increased 39% as compared to Vioxx's competitor, Celebrex.
- 44. At all times relevant to this litigation, Defendant Merck had a significant market share based upon claims of Vioxx's efficacy, a very aggressive marketing program which involved financial incentives to sales teams, infusion of some 700 new sales representatives, and a massive advertising and sampling program.
- 45. If Merck had not engaged in this conduct, consumers, including Plaintiff, would have known the true risks of ingesting Vioxx and would have switched from Vioxx to safer products or refrained wholly from its use.
- 46. The marketing strategies of the Merck targeted Plaintiff and the other users to induce them to purchase Vioxx. At the time the Merck distributed, manufactured and marketed Vioxx, Merck intended that Plaintiff would rely on the marketing, advertisements and product information propounded by Merck, as well as Merck's omission of relevant negative information from such materials.

- 47. From the initial marketing of Vioxx until April 2002, the safety label for Vioxx set forth an explicit warning concerning "Gastrointestinal (GI) Effects." Specifically, the safety label warned of the "Risk of GI Ulceration, Bleeding, and Perforation." Nowhere within the safety label did Merck make full or adequate disclosure of the cardiovascular safety issues related to Vioxx.
- 48. After reviewing the results of the VIGOR study and other available data from controlled clinical trials, the FDA consulted with its Arthritis Advisory Committee. In April 2002, pursuant to the review by the FDA and resultant instructions, Merck implemented labeling changes for Vioxx to reflect the findings from the VIGOR study. The labeling changes included information about the occurrence of cardiovascular events, including heart attack and stroke, in some patients. At no time did the safety label disclose the level of risk that consumers were subjected to as a result of their ingestion of Vioxx. In fact, Merck continued to stand by the "safety profile" of Vioxx.
- 49. The April 2002 labeling changes were insufficient to put the consuming public on notice of the extent of the risk of adverse health effects that use of Vioxx presented.
- 50. Thus, despite knowledge in its clinical trials and post-marketing reports, studies and information relating to cardiovascular-related adverse health effects, Merck promoted and marketed Vioxx as safe and effective for persons such as Plaintiff.
- 51. Merck failed to reveal the true connection between use of Vioxx and cardiovascular events until September 30, 2004.
- 52. On June 2, 2002, Plaintiff Martin underwent surgery at the Dartmouth-Hitchcock Medical Center to repair the left anterior cruciate ligament tear in her left leg; the surgical procedure being performed under the care of Dr. Charles F. Carr, MD.

- 53. On or December 19, 2002, Martin was prescribed Vioxx by Dr. Roshini Pinto-Powell, M.D. of the Dartmouth-Hitchcock Medical Center.
- 54. Dr. Powell, Dr. Carr and the Dartmouth-Hitchcock Medical center knew or should have known of the dangers and contraindications posed by the prescription to and subsequent use by Plaintiff Martin of the drug Vioxx, but prescribed the drug without regard thereto.
- 55. Martin continued to take the prescribed Vioxx through and including March of 2004.
- 56. On or about March 10, 2004, Martin experienced severe bleeding and hemorrhaging, and was admitted to Massachusetts General Hospital, on an outpatient basis, and then sent home on an out-patient basis.
- 57. On or about March 11, 2004, Martin again experienced major gastrointestinal bleeding, was admitted again to Massachusetts General Hospital for emergency treatment, said treatment requiring the transfusion of 12 units of packed red blood cells to deal with the blood loss and hemorrhaging.
- 58. Martin continues to suffer serious and debilitating health conditions as a result of the use of the Vioxx prescribed, including but not limited to elevated risk of stroke, elevated blood pressure, complications during two (2) different medical with respect to procedures in relation to Plaintiff's left knee, and other cardiac issues.

COUNT I

(Misrepresentation)

59. Plaintiff incorporates by reference all preceding paragraphs as if fully set forth herein.

- 60. Defendant Merck intentionally employed deceptive representations as to the risks and side effects of Vioxx in the marketing, promotion and sale of the drug to consumers, as set forth above.
- 61. Defendant Merck's wrongful conduct included the issuance of the false and misleading representations and omissions of material facts regarding Vioxx's capabilities and the side effects of Vioxx upon which Plaintiff relied.
- 62. Defendant Merck failed to sell Vioxx in the manner and of the nature advertised or offered, and was unable to provide Vioxx in accordance with other terms or conditions.
- 63. The fraudulent practices of Defendant Merck have directly, foreseeably, and proximately caused damages and injury to Plaintiff.
 - 64. Defendants Merck's conduct, in part, caused Plaintiff to acquire and ingest Vioxx.
 - 65. By reason of Defendant Merck's unlawful conduct, Plaintiff has suffered losses and is entitled to damages.

COUNT II

(Medical Monitoring)

- 66. Plaintiff incorporates by reference all preceding paragraphs as if fully set forth herein.
- 67. As a direct and proximate result of Defendants' acts and omissions as set forth herein, Plaintiff was exposed to a hazardous substance and, as a result, now suffers a significantly increased risk of contracting further serious injury or latent disease,

including heart attack and stroke. This increased risk makes periodic diagnostic and medical examination reasonable and necessary. Easily administered, cost-effective monitoring and testing procedures exist which make the early detection and treatment of such injuries or disease possible and beneficial.

- 68. The recommended testing and monitoring procedures will be subject to expert testimony at the time of trial.
- 69. The increased susceptibility to injuries and irreparable threat to the health of Plaintiff resulting from Plaintiff's exposure to Vioxx can only be mitigated or addressed by the creation of a comprehensive medical monitoring program.
- 70. Plaintiff has no adequate remedy at law in that monetary damages alone cannot compensate for the continuing nature of the harm to her, and a monitoring program which notifies her of possible injury and aids in the diagnosis and treatment of these injuries can prevent the greater harms which may not occur immediately and which may be preventable if proper research is conducted and the health risks are diagnosed and treated before they occur or worsen.
- 71. The susceptibility of Plaintiff to heart attacks, strokes, and other disorders is a result of her use of Vioxx. Early detection and diagnosis of these conditions is clinically invaluable because it can prevent and/or significantly delay resulting pain, suffering and/or death.
- 72. In the absence of a court-approved and supervised medical monitoring program, Plaintiff will not receive prompt medical care which could detect injury and disease and prolong her productive life, increase her prospects for improvement, and minimize disability.

(Unjust Enrichment as to Merck)

- 73. Plaintiff incorporates by reference all preceding paragraphs as if fully set forth herein.
- 74. As a direct proximate, and foreseeable result of Defendant Merck's acts and otherwise wrongful conduct, Plaintiff was economically harmed. Defendant Merck profited and benefited from the sale of Vioxx, even as Plaintiff suffered the noted harm.
- 75. Defendant Merck has voluntarily accepted and retained these profits and benefits, derived from Plaintiff with full knowledge and awareness that, as a result of Defendant Merck's unconscionable and intentional wrongdoing, Plaintiff, was not receiving products of the quality, nature, fitness, or value that had been represented by Defendant Merck or that a reasonable consumer would have expected. Plaintiff purchased medicine that she expected would improve her health, and instead found that her health was instead negatively affected.
- 76. By virtue of the conscious wrongdoing alleged in this Complaint, Defendant Merck has been unjustly enriched at the expense of Plaintiff, who is entitled to in equity, and hereby seeks, the disgorgement and restitution of Merck's wrongful profits, revenue. and benefits, to the extent, and in the amount, deemed appropriate by the Court; and such other relief as the Court deems just and proper to remedy Merck's unjust enrichment.

COUNT IV

(Medical Malpractice as against Defendants Pinto-Powell and Carr)

77. Plaintiff incorporates by reference all preceding paragraphs as if fully set forth herein.

- 78. Defendant Dr. Pinto-Powell and Dr. Charles Carr are medical doctors licensed to deliver medical services to the public at large within the State of New Hampshire.
- 79. Plaintiff on multiple occasions was treated by Defendants Pinto-Powell and Defendant Carr and provided prescriptions by Defendant Pinto-Powell.
- 80. Defendant Pinto-Powell and Defendant Carr breached the standard of medical care, or in other words, was negligent in the delivery of medical services and treatment as set forth above and thus breached the standard of due care and diligence in the medical treatment of the Plaintiff.
- 81. Plaintiff Martin has suffered injuries from the medical services and treatment received from Defendant Pinto-Powell and Defendant Carr.
- 82. Defendant Pinto-Powell and Defendant Carr acted negligently in providing medical services and treatment to Plaintiff Martin, resulting in damages and injuries to Plaintiff Martin.

COUNT V

(Breach of Contract as against Defendant Dartmouth-Hitchcock Medical Center)

- 83. Plaintiff incorporates by reference all preceding paragraphs as if fully set forth herein.
- 84. Defendant Dartmouth sought services from the physicians and medical staff at Defendant Dartmouth's facilities and entered into a contract with Defendant Dartmouth for treatment of Plaintiff's medical condition.
- 85. Defendant Dartmouth failed to provide medical services in a professional and reasonable manner in accordance with standard practices and requirements.

- 86. Defendant Dartmouth failed to warn Plaintiff of the dangers of Vioxx, even though Defendant Dartmouth and/or its medical professionals and staff knew or had reason to know of the dangers of Vioxx and thus failed to deliver the medical and supporting services in accordance with the agreement between the parties and/or in accordance with standard medical practice.
- 87. Defendant Dartmouth failed to warn Plaintiff of the dangers of Vioxx, even though Defendant Dartmouth and/or its medical professionals and staff knew or had reason to know of the dangers of Vioxx in violation of state law.
- 88. Defendant Dartmouth breached the contract between Defendant Dartmouth and Plaintiff Martin resulting in substantial injury, harm and damages to Plaintiff Martin.

COUNT VI

(Unjust Enrichment as against Defendant Dartmouth-Hitchcock Medical Center))

- 89. Plaintiff incorporates by reference all preceding paragraphs as if fully set forth herein.
- 90. As a direct proximate, and foreseeable result of Defendant Dartmouth-Hitchcock Medical Center's acts and otherwise wrongful conduct, Plaintiff was economically harmed. Defendant Dartmouth-Hitchcock Medical Center profited and benefited from the sale of Vioxx, even as Plaintiff suffered this harm.
- 91. Defendant Dartmouth-Hitchcock Medical Center has voluntarily accepted and retained these profits and benefits, derived from Plaintiff with full knowledge and awareness that, as a result of Defendant's unconscionable and intentional wrongdoing, Plaintiff was not receiving products of the quality, nature, fitness, or value that had been represented by Defendant or that a reasonable consumers, expected. Plaintiff purchased

medicine that she expected would improve her health, and instead found her health negatively affected.

92. By virtue of the conscious wrongdoing alleged in this Complaint, Defendant Dartmouth has been unjustly enriched at the expense of Plaintiff, who is entitled to in equity, and hereby seek, the disgorgement and restitution of Defendant's wrongful profits, revenue, and benefits, to the extent, and in the amount, deemed appropriate by the Court; and such other relief as the Court deems just and proper to remedy Defendant's unjust enrichment.

COUNT VII

(Medical Malpractice as against Defendant Millet)

- 93. Plaintiff incorporates by reference all preceding paragraphs as if fully set forth herein.
- 94. Defendant Dr. Peter Millet is medical doctors licensed to deliver medical services to the public at large within the Commonwealth of Massachusetts.
- 95. Plaintiff on multiple occasions was treated by Defendant Millet and provided prescriptions by Defendant Millet.
- 96. Defendant Millet breached the standard of medical care, or in other words, was negligent in the delivery of medical services and treatment as set forth above and thus breached the standard of due care and diligence in the medical treatment of the Plaintiff.
- 97. Plaintiff Martin has suffered injuries from the medical services and treatment received from Defendant Millet.
- 98. Defendant Millet acted negligently in providing medical services and treatment to Plaintiff Martin, resulting in damages and injuries to Plaintiff Martin.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for relief as follows on each and every Count of its Complaint:

- General damages in amount to be proven at trial and in excess of the jurisdictional minimum of this Court;
 - 2. Pre-judgment and post-judgment interest as provided by law;
 - 3. Full refund of all purchase costs Plaintiff paid for Vioxx;
- 4. Compensatory damages in excess of the jurisdictional minimum of the Court, according to proof;
- Consequential damages in excess of the jurisdictional minimum of the Court,
 according to proof;
 - 6. Disgorgement of all profits associated with Vioxx;
- 7. Injunction requiring Defendant to fund a medical monitoring program to address the needs of the Plaintiff associated with the use of Vioxx; and
- 8. Such further relief as this Court deems necessary, just and proper.

 PLAINTIFF DEMANDS A TRIAL BY JURY ON ALL COUNTS AND ISSUES SO
 TRIABLE

Plaintiff,

By her attorneys,

Andrew J. Tine BBO#633639

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